

MAR - 5 1997

(I) **510(k) Summary:**

This summary is submitted in conformance with the format described in the 21 CFR Part 807.92 interim rule dated April 28, 1992.

(1) **Submitted By:**

MedCare Medical Group, Inc.
234 Old Homestead Highway
E. Swanzey, NH 03446

Contact Person:

Craig J. Bell
Director of Research and Development
(603)352-3230

(2) **Name of Device:**

Biopsy Tray

Classification Name:

Unknown

(3) **Identification of Predicate Devices:**

Medical Procedures Inc.
2223 Eastern Ave.
Baltimore, MD 21231

Basic Stereotactic Core Kit
Cat. No. MP-002

(4) **Description of Device Subject to Premarket Notification:**

The Biopsy Tray is intended to conveniently provide the auxiliary components utilized during biopsy procedures. The components are items that are commonly used during a variety of biopsy procedures. The Biopsy Tray provides the convenience of having these items packaged in a single package, sterile, and ready to use. The kits are provided sterile, disposable, and for single patient use.

(5) **Intended Use of the Device:**

The Biopsy Tray is a single patient, single use, disposable device which is intended to conveniently provide components for the administration of biopsy procedures.

(6) **Technological Characteristics**

The MedCare Biopsy Tray is similar to the predicate device in that both of the device provide a variety of components for the convenient administration of biopsy procedures. Both devices provide flexibility in componentry selection for kit customization, which provides the maximum convenience for the customer.